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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/046,727	01/17/2002	Graham D. Cook	1142.0125-00	2584

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EXAMINER

KIM, JENNIFER M

ART UNIT PAPER NUMBER

1617

DATE MAILED: 05/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/046,727

Applicant(s)

Cook et al.

Examiner

Jennifer Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 February 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 6-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,6-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

RD

DETAILED ACTION

The response filed February 22, 2005 have been received and entered into the application.

Action Summary

The rejection of claims 2 and 6 under 35 U.S.C. 102(b) as being anticipated by White (U.S.Patent No. 5,431,916) is being maintained for the reasons stated in the previous office action.

The rejection of claims 2 and 6-13 under 35 U.S.C. 103(a) as being unpatentable over Sunshine et al. (U.S.Patent No. 4,522,826) of record in view of White (U.S.Patent No. 5,431,916) is being maintained for the reasons stated in the previous office action.

The rejection of claims 1, 2 and 7-13 under 35 U.S.C. 103(a) as being unpatentable over Sunshine et al. (U.S.Patent No. 4,522,826) of record in view of Weng et al. (U.S.Patent No. 5,512,300) and further in view of Ouali et al. (U.S.Patent No. 6,287,600) is being maintained for the reasons stated in the previous office action.

Response to Arguments

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Applicants' arguments filed February 22, 2005 have been fully considered but they are not persuasive. With respect to the argument **regarding anticipation rejection under 35 USC 102**, Applicants essentially argue that anticipation rejection under 35 USC 102 is improper because White may list the various compounds recited in the instant claims, White fails to specifically disclose the claimed composition and White does not provide any guidance to specifically pick and choose ibuprofen and diphenhydramine from a laundry list of pharmaceutically acceptable actives disclosed therein. This is not persuasive because White illustrates the composition comprising ibuprofen and diphenhydramine and it can be formulated in soft gelatin capsule with polyethylene glycol. Accordingly, White teaches all of the limitation set forth in the rejected claims. Therefore, this illustration and the teaching clearly anticipate Applicant's invention set forth in claims 2 and 6. With respect to the Argument **regarding rejection under 35 USC 103**, Applicants essentially argue that there is no teaching or suggestion in any of the cited references to modify their teachings to arrive at the claimed invention and Sunshine fails to specifically disclose the claimed composition including polyethylene glycol in combination with ibuprofen and diphenhydramine and note that there is nothing in Sunshine that would suggest specifically using polyethylene glycol, listed among five genres and six species of binder, in composition of the claimed invention. This is not persuasive because the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary

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skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Sunshine et al. teach a pharmaceutical composition comprising ibuprofen and diphenhydramine elicits an enhanced analgesic and /or anti-inflammatory response and also teach that polyethylene glycol is an acceptable carrier to the composition. White teaches the advantage of soft gelatin capsules as being convenient portable and easy to swallow and polyethylene glycol is routinely incorporated in the combination. Therefore, one would have been motivated to formulate Sunshine composition into soft gelatin capsules in order to provide the advantages of soft gelatin capsule with well-known ingredient (polyethylene glycol) routinely formulated with the combination. Applicants argue that the composition disclosed in Sunshine may be formulated as a two-layered tablet but fails to perceive any problems with having ibuprofen and diphenhydramine in the same composition and based on the alleged success of a composition containing both ibuprofen and diphenhydramine, one of ordinary skill in the art would have no motivated to separate the two. This is not persuasive because Sunshine et al. teach the composition comprising ibuprofen and diphenhydramine can be formulated in a tablet form or two or more layered tablets. Quali et al. teach that bilayer tablets have advantage to separate a first drug and a second drug into physically discrete regions of a single dosage form. Therefore, one would be motivated to separate ibuprofen and diphenhydramine bilayer tablet into a physically discrete regions of a single bilayer tablets in order to achieve one of advantages of bilayer tablets taught by Quali et al.

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Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

In view of the above Office Action of September 22, 2004 is deemed proper and asserted with full force and repeated to obviate applicants' claims.

None of the claims are allowed.

THIS ACTION IS MADE FINAL. Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

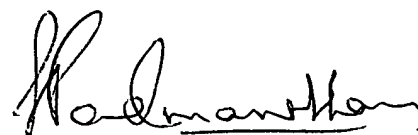
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Sreenivasan Padmanabhan
Supervisory Examiner
Art Unit 1617

Jmk
May 13, 2005